DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 16 2004

SP 04P-0383/CP1

Ancare New Zealand Ltd.
Attention: Robert Holmes, Business Development Manager
First Floor, 17 Shea Terrace
Takapuna, Auckland
PO Box 36240, Northcote
Auckland, New Zealand

Dear Mr. Holmes:

We refer to your Suitability Petition filed August 31, 2004, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product with a concentration (change of strength) that differs from that of an approved new animal drug. The proposed pioneer product is Merial's Ivomec® (ivermectin) Pour-On for Cattle which is intended for use in cattle (NADA 140-841).

Your proposed product differs from the pioneer product in concentration (change of strength). The proposed generic product is a solution, which can be administered topically the same as the pioneer. The proposed generic product is intended to deliver the same amount of active ingredient per pound of body weight, and is intended for individual animal treatment, as is the pioneer solution.

Change of strength is one of the five variances in the pioneer product which can be considered through a Suitability Petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended. We are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed generic product.

Your Suitability Petition is approved. Approval of the Suitability Petition does not alter the requirements for approval of the ANADA, nor assure approval of the ANADA. Please include a copy of this letter in your generic application.

An *in vivo* bioequivalence study to demonstrate bioequivalence between the pioneer and the generic products will be required. We recommend that you submit protocols for our evaluation before initiating any studies. The *in vivo* bioequivalence study must indicate

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equal dosing between pioneer and generic products.

The pioneer product is protected by an exclusivity that expires on November 24, 2006, for the use of ivermectin to prevent reinfection with *Oesophagostomum radiatum* and *Dictyocaulus viviparous* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *C. surnabada* for 14 days after treatment; and *Damalinia bovis* for 56 days after treatment.

We will conduct a definitive labeling review when the ANADA for the proposed generic product is submitted to the Center. The generic labeling should be a verbatim copy of the approved labeling for the pioneer, with certain allowable differences, such as manufacturer's tradename and the changes approved in this petition.

You may contact Dr. Lonnie W. Luther, Generic Animal Drug Team, telephone 301-827-8549, for any questions on the specific requirements for the ANADA submission.

Sincerely yours,

Steven D. Vaughn DVM

Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine